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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,911	02/05/2004	Daniella Licht	68920-A/JPW/GJG/JBC	5239

7590 05/22/2007

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,911	LICHT ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on 05 February 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 4-1-05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of preliminary amendment dated 2-5-04 and IDS dated 7-204 & 4-1-05 is acknowledged.

Claims 1-55 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2001/0005512 to Anderson in view of Remingtons' Pharmaceutical Sciences (1990) OR US 6,419,953 to Qiu et al and Remingtons' Pharmaceutical Sciences (1990).

Anderson teaches a pharmaceutical composition comprising valproate compounds such as divalproex sodium as an active agent. For the dosage forms

containing the active agent, Anderson teaches tablet formulations comprising the active agent and hydroxypropyl cellulose, which read on the instant components I) and ii). For the instant filler, Anderson teaches microcrystalline cellulose and lactose in the above dosage form. For the instant lubricant, Anderson teaches magnesium stearate (paragraphs 0107 – 0114). Anderson also teaches the active agents for the same treatment i.e., epilepsy and bipolar disorder (col. 1-2). While instant claims recite an immediate release composition in the preamble, the claims do not distinguish or specify as to what the release rate is or how quickly and how much of the active agent is released. Accordingly, the preamble does not add any patentable weight to the claimed composition. Further, Anderson teaches the various tabletting ingredients as percentages of the total weight of the tablet as opposed to the amounts. However, the tablets of Anderson are prepared in the same manner (compression tablets) as that claimed in the instant i.e., admixing the predetermined amounts and compressing the tablets, as in claim 46. Anderson also teaches the excipients for the same purpose i.e., filler, lubricant etc and accordingly, optimizing the amount of an excipient with an expectation the desired tabletting effect such as lubrication, increasing the bulk (with a filler) etc., would have been within the scope of a skilled artisan.

Qiu et al (Qiu) teaches controlled release composition comprising an anti-epileptic agent, valproic acid or its salts such as an ester, amide etc., prepared by intimately mixing the components of the composition and compression method (lines bridging col. 2-3 & col. 5, L 8-20). The composition, in the form of tablets, contains

hydroxypropyl methylcellulose (examples formulations) and excipients such as magnesium stearate, lactose, microcrystalline cellulose (col. 3, L 1-53 & col. 5).

Both Anderson and Qiu fail to teach the claimed disintegrant in the composition comprising valproic acid or its salts. However, both the references are directed to preparing compressed dosage forms for a controlled release of active agent. As the examiner has already mentioned in the previous paragraphs, instant claims do not recite a specific release rate and therefore the preamble limitation of 'immediate release" do not impart any patentable weight.

Remingtons' Pharmaceutical Sciences (Remingtons') teach oral dosage forms, particularly, compressed tablets comprising the tabletting excipients such as diluents, binders, disintegrants, glidants etc (pages 134-1637). Remingtons' teach that a substance or a mixture of substances is added to a tablet so as to facilitate its break up or disintegration after administration (page 1637). Among the disintegrants, Remingtons' teach the instant claims sodium starch glycolate or croscarmellose sodium as super Disintegrants, which are also claimed in the instant application (page 1637). Further, Remingtons' suggests that the disintegrant may be added to the active ingredients along with the lubricants, fillers etc., or may be divided into two portions, in which one portion is added prior to granulation and the other is added and the reminder mixed with lubricants before compression. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a disintegrant such as sodium starch glycolate or croscarmellose sodium, of Remingtons' in the

compression tabletting composition of Anderson or Qiu because Remingtons' teach that the disintegrants or super disintegrants allow the quick break up of the tablet for its rapid dissolution and super disintegrants such as croscarmellose sodium are even more effective because of their activity even at low amounts and high swelling. Accordingly, depending on the desired rapidity of drug release, a skilled artisan would have employed an appropriate amount of a disintegrant in the composition of Anderson or Qiu. Further, with respect to the composition claims containing specific amounts of fillers, active agent and the disintegrants, absent any unexpected result optimizing the amounts of each of the active agent or the tabletting ingredients (lubricant, filler, disintegrant, release polymer) so as to achieve the desired release rate would have been within the scope of a skilled artisan.

Information Disclosure Statement

The information disclosure statement filed 7-2-04 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a

column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. **Instant IDS does not contain a PTO-1449 listing all the prior art references for consideration.** The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
April 30, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER